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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/885,189 | 06/21/2001 | Chris Somerville | 056100-5022-08 | 7809 |

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

1S

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------------|-------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/885,189 | SOMERVILLE ET AL. |
| | Examiner | Art Unit |
| | Elizabeth F. McElwain | 1638 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 May 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 13,26,27,31 and 35-41 is/are pending in the application.
 - 4a) Of the above claim(s) 38 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 13,26,27,31 and 35-41 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 June 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed May 12, 2003 has been entered.

Claims 13, 28-30 and 32-34 have been cancelled.

Claims 26, 27, 31, 35 and 36 are newly amended.

1. Applicant's election of Group IV, drawn to Canola oil, in Paper No. 14 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 26, 27, 31, 35-37 and 39-41 are pending and are examined to the extent the claims are drawn to Canola oil. Claim 38 is withdrawn as drawn to a non-elected invention.

Specification

2. The disclosure is objected to because of the following informalities: The specification recites patent application numbers without referring to the issued U.S. Patent number. See pages 3 and 10, for example.

Appropriate correction is required.

Claim Objections

3. Claim 36 is objected to because of the following informalities: the claim recites non-elected plant species. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 26, 27, 31, 35-37 and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26 and 27, and all claims dependent thereon are indefinite in the recitation of “seeds of the same plant”, since the seeds having increased hydroxylated fatty acid content could not be from the same plant, but could be from a plant of the same species.

Claim 36 is indefinite in the recitation of “Canola”, since the specification does not clearly set forth what is intended by “Canola”, while the specification does suggest that this is considered to be a variety of rapeseed (see page 40, lines 17-18). In addition, while the name “Canola” is widely used in the art, it remains unclear that it is defined in a consistent way that would enable one skilled in the art to determine what varieties would be included by this term. Furthermore, the claim separately recites “rapeseed”, which also suggests that the terms “Canola” and “rapeseed” do not encompass the same plants. It is suggested that applicant amend the claims to recite “*Brassica napus*”, instead of “Canola” and that “rapeseed” also be deleted from the claim.

Claim 39 is indefinite in that it does not further limit the claims from which it depends.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26, 27, 31, 35-37 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to oil from a plant that has been transformed with a nucleic acid sequence that encodes a fatty acid hydroxylase, including from a Canola plant, wherein said oil has a hydroxylated fatty acid content that is increased compared to the hydroxylated fatty acid content from an oil obtained from seeds of the same plant that has not been transformed with a nucleic acid sequence that encodes a fatty acid hydroxylase.

However, there is no description provided regarding the level of hydroxylated fatty acid content that is present in the non-transformed plant to which the comparison is made, wherein said non-transformed plant could be of any of a multitude of plant species. The specification does not set forth what the level of each and every hydroxylated fatty acid would be from plant species that have not been transformed with the nucleic acid of the claim. Therefore, it is impossible to determine what the characteristics are of oil having an increased content of hydroxylated fatty acids relative to said untransformed plant. In addition, the specification

does not provide any further written description that would allow one skilled in the art to distinguish the oil that is claimed from any oil that comprises at least one hydroxylated fatty acid of any amount.

In fact, the specification only describes oil that is obtained from seeds of *Arabidopsis* plants that have been transformed with a nucleic acid sequence encoding a fatty acid hydroxylase, wherein said oil has the hydroxylated fatty acids: ricinoleic, lesquerolic, densipolic and auricolic. While, the transformation of any other plant species would likely result in a different combination of hydroxylated fatty acids, and the levels of hydroxylated fatty acids in any of the transformed plants would depend upon the level of precursors, as well as the level of gene expression of the fatty acid hydroxylase gene in that particular plant. The specification fails to provide a written description of any other oils having increased levels of hydroxylated fatty acids from any other plant species, including from Canola, or that include any of the other hydroxylated fatty acids that are set forth in claim 36. Furthermore, the recitation of nucleic acid sequences in the claims does not describe the physical characteristics of the oil that is obtained from a plant that comprises that sequence, given the different precursors present in different plant species, and the varied levels of expression of the gene in different transformants, for example.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

7. Claims 26, 27, 31, 35-37 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for oil obtained from *Arabidopsis* that has been transformed with a nucleic acid sequence encoding a fatty acid hydroxylase, which comprises ricinoleic, lesquerolic, densipolic, and auricolic acid, does not reasonably provide enablement for oil from a plant that has been transformed with a nucleic acid sequence that encodes a fatty acid hydroxylase, including from a Canola plant, wherein said oil has a hydroxylated fatty acid content that is increased compared to the hydroxylated fatty acid content from an oil obtained from seeds of the same plant that has not been transformed with a nucleic acid sequence that encodes a fatty acid hydroxylase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a oil obtained from a Canola plant that has been transformed with a nucleic acid encoding a fatty acid hydroxylase, wherein said oil comprises one or more hydroxylated fatty acids that are set forth in claim 36. However, the specification fails to disclose any oil having these characteristics other than that of *Arabidopsis*, which comprises five of the hydroxylated fatty acids listed in claim 36. The specification does not disclose any oil obtained from a transformed plant having any of the other hydroxylated fatty acids listed in claim 36. In addition, the specification fails to provide guidance with regard to the transformation and evaluation of oil from other plant species.

DeLuca teaches the unpredictability of altering plant biosynthetic pathways by genetically engineering plants, given a lack of understanding of plant metabolic pathways and their in vivo regulation (page 225N), and states that “on many occasions desired goals have been impossible to achieve” (page 228N). In addition, Topfer et al specifically teach the unpredictability of altering hydroxylated fatty acids in a plant transformed with a fatty acid hydroxylase gene (page 684, the first column). Topfer et al teach that transformed tobacco plants had extremely low levels of ricinoleic acid and that this was probably due to factors present in tobacco tissues that did not allow the hydroxylated fatty acid to accumulate, and state that additional enzymes are probably required for the stable formation of ricinoleic acid at higher levels. Thus, the ability of other plant species to accumulate hydroxylated fatty acids at increased levels relative to non-transformed plants is highly unpredictable in light of the many other factors present in plant cells and tissues that affect this production.

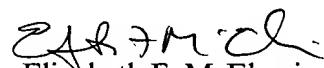
Therefore, given the unpredictability of the genetic engineering of plants for the production of increased levels of hydroxylated fatty acids; the lack of work examples other than that of Arabidopsis oil having four of the hydroxylated fatty acids; the absence of guidance with regard to the production and evaluation of other plant oils and other hydroxylated fatty acids; and given the breadth of the claims which encompass oil from any plant species and having any or all of the hydroxylated fatty acids listed in claim 36; and given the state of the art which showed limited success in only one other plant species; it would require undue experimentation by one skilled in the art to make and/or use the invention, as claimed.

The claims are deemed free of the prior art of record given that the prior art fails to teach oil obtained from a plant, including a Canola plant, that has been transformed with a nucleic acid encoding a fatty acid hydroxylase of the claims, wherein said oil has an increased level of hydroxylated fatty acids relative to a non-transformed plant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is 703-308-1794. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Elizabeth F. McElwain
Primary Examiner
Art Unit 1638

EFM
July 24, 2003